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25-Oct-11

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Official Contact: Izhak Fabian - CEO

Proprietary or Trade Name: ClearPath Upper GI

Common/Usual Name: Irrigation/evacuation system

Classification Name/Code: FDS – Endoscope and accessories, flexible/rigid
CFR 876.1500
Class 2

Device: ClearPath Upper GI

Predicate Devices: K093779 – EasyGlide – ClearPath Upper GI

Device Description:
The Clearpath Upper GI was cleared under K093779, we have modified the design.

The ClearPath Upper GI includes one suction tube + tip, one irrigation tube + tip, and a sleeve to attach to the endoscope. The ClearPath Upper GI is connected to the ClearPath Controller and the ClearPath Tubing (K091305) and allows for irrigation and evacuation of debris from the upper gastrointenstinal tract during an endoscopic procedure. The device can accommodate several sizes and configurations of endoscopes with a change in the attachment ring.

Indications for Use:
The ClearPath Upper GI is intended for irrigating or cleaning the upper digestive tract and evacuating the irrigation fluid, blood and bile in the upper GI tract during endoscopic procedures.

It is for use only by trained medical personnel located in hospitals, clinics, and doctors' offices.

Patient population:
Individuals undergoing endoscopic procedures.

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Environment of Use:
Hospitals, clinics, and doctors' offices.

Performance testing:
We have performed bench and animal testing to verify that the ClearPath Upper GI performs as expected in conjunction with standard endoscopes and with the cleared ClearPath controller and tubing K0910305. The tests include:

- Dimensional testing
- Strength testing
- Functional testing
- Mechanical testing
- Compliance with endoscopes

The animal testing evaluated:

- Any sign of dislodgement of the tip from the endoscope during the procedure
- Ease of maneuverability and advance in the GI tract
- Quality of visibility
- Quality of irrigation
- Any sign of occlusion or interruption to continuous suction.
- Quality of evacuation of blood, bile, and other bodily fluid and matter

All testing demonstrated that the modified ClearPath Upper GI disposable performed to its specifications and / or was equivalent to the predicate.

Summary of substantial equivalence:
We demonstrate that the modified ClearPath Upper GI is substantially equivalent to the predicate in design and performance characteristics:

- **Indications** – Identical to predicate K093779: Cleaning, irrigating, and evacuating the upper GI tract during endoscopic procedures

- **Technology** – Identical to predicate: Single use disposable, applied over a standard endoscope, works in conjunction with the Clearpath Controller (K091305) to facilitate cleaning of the upper GI tract by irrigation and evacuation.

- **Environment of use** – Identical to predicate: Hospitals, clinics, and doctors' offices.

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- **Materials** – Materials were either identical to the predicate or shown to comply with ISO 10993-1

- **Difference** – there are no substantial differences or new features in the proposed device compared to the predicate which raises any new safety or efficacy issue

Comparative Table - Compares the predicates and the proposed modified device

	Proposed device	**Predicate device**
	EasyGlide	**K093779 EasyGlide**
Device	**Clearpath Upper GI**	**Clearpath Upper GI**
Design	Used as an add-on to standard endoscopes for irrigation and evacuation. Attaches along the endoscope leaving the working channel free.	Used as an add-on to standard endoscopes for irrigation and evacuation. Attaches along the endoscope leaving the working channel free.
Indications for use	The ClearPath Upper GI is intended for irrigating or cleaning the upper digestive tract and evacuating the irrigation fluid, blood and bile in the upper GI tract during endoscopic procedures. It is for use only by trained medical personnel located in hospitals, clinics, and doctors' offices.	The ClearPath Upper GI is intended for irrigating or cleaning the upper digestive tract and evacuating the irrigation fluid, blood and bile in the upper GI tract during endoscopic procedures. It is for use only by trained medical personnel located in hospitals, clinics, and doctors' offices.
Environment of use	Hospitals, clinics, and doctors' offices.	Hospitals, clinics, and doctors' offices.
Prescriptive	Yes, only trained medical personnel	Yes, only trained medical personnel
Principle of operation	Distal attachment to an endoscope, sleeve ensuring attachment along entire length, suction and irrigation tubes running along the endoscope, suction and irrigations heads at the distal tip. Enables irrigation and suction at any time during the procedure without removing any tools which may be inserted in the endoscope's working channel.	Distal attachment to an endoscope, sleeve ensuring attachment along entire length, suction and irrigation tubes running along the endoscope, suction and irrigations heads at the distal tip. Enables irrigation and suction at any time during the procedure without removing any tools which may be inserted in the endoscope's working channel.
accessories	ClearPath Controller and ClearPath Tubing (K091305)	ClearPath Controller and ClearPath Tubing (K091305)
Distal tip design	Multi irrigation holes Distal suction hole	Multi irrigation holes Distal suction hole
Material	Comply with ISO 10993	Comply with ISO 10993
Performance	Like the predicate, the modified device was tested for compliance and performance under the working conditions as prescribed by the ClearPath Controller (K091305). Comparative animal test compared functionality to that of the predicates	As detailed in K093779 tests were performed to demonstrate the performance of the device under the working conditions as prescribed by the ClearPath Controller (K091305).
Disposable	Single patient, use, disposable	Single patient, use, disposable
Packaged	Clean, non-sterile	Clean, non-sterile

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

EasyGlide Ltd.
% Mr. Paul Dryden
President
ProMedic, Inc.
24301 Woodsage Drive
BONITA SPRINGS FL 34134

MAY 16 2012

Re: K113166
Trade/Device Name: ClearPath Upper GI
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FDS
Dated: April 15, 2012
Received: April 17, 2012

Dear Mr. Dryden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K113166 (To be assigned)

Device Name: ClearPath Upper GI

Indications for Use:

The ClearPath Upper GI is intended for irrigating or cleaning the upper digestive tract and evacuating the irrigation fluid, blood and bile in the upper GI tract during endoscopic procedures.

It is for use only by trained medical personnel located in hospitals, clinics, and doctors' offices.

Prescription Use XX (Part 21 CFR 801 Subpart D) **or** **Over-the-counter use __** (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K113166